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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,042	01/21/2004	Jei-Fu Shaw	08919-099001 / 09A-910930	3786
26161	7590	07/28/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			KUMAR, VINOD	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/763,042

Applicant(s)

SHAW ET AL.

Examiner

Vinod Kumar

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-17, 20 and 22-33 is/are pending in the application.
- 4a) Of the above claim(s) 16, 17 and 20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-25 is/are allowed.
- 6) ☒ Claim(s) 6-15 and 26-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6-15, 22-25 and newly added claims 26-33 are examined. All previous rejections not set forth below have been withdrawn in view of amendments and/or persuasive arguments filed May 18, 2006.

Claim Objections

2. In claim 6, line 3, insert --which has-- before “at” and after “sequence”.

Claim Rejections - 35 USC § 112

3. Claims 7, 9, 11, 13, 15 and newly added claims 27 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being Indefinite in its recitation “hybridizes to a probe of SEQ ID NO: 20”, which is confusing since it is not exactly clear what is considered a probe of SEQ ID NO: 20. It is suggested to insert --comprising the sequence-- before “of” and after “probe”.

4. Claims 6-14 remain and claim 15 and newly added claims 26-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising a sequence that encodes the polypeptide of SEQ ID NO: 9, does not reasonably provide enablement for a nucleic acid that encodes for a polypeptide which has less than 100% sequence identity to SEQ ID NO: 9, for the

reasons of record stated in Office action mailed February 13, 2006. Applicants traverse the rejection in the paper filed May 18, 2006.

Applicants argue that the specification teaches how to use polypeptides that have the activity of increasing the sensitivity of a plant to an environmental factor, there is no question that the specification enables one skilled in the art to use each of the polypeptides encoded by the claimed nucleic acids (response, page 12, lines 11-15). Further, Applicants first assert that Guo et al. teaches that 34% of the random replacements led to functional inactivation, then argue that one of ordinary skill can expect, based on Guo et al.'s teachings, to find about 76% of random substitutions in any given protein to result in mutated proteins with full or nearly full activity (response, page 12, lines 4-7). Further, given the information provided in the specification regarding tubby domains F-box, TUB motifs, and residues conserved in SEQ ID NO: 9/AtTLP9, one of ordinary skill in the art would know to avoid these conserved domains/residues for making conservative changes there, thereby making the predictability of success even higher than the 76% in Guo et al. (response, page 13, lines 16-20).

Applicant's arguments were fully considered but were not persuasive. Neither the state of prior art nor the specification provide guidance on which region(s) of SEQ ID NO: 20 is able to tolerate deletions, additions or substitutions of one or more amino acid without abrogating its activity which results in increased sensitivity to environmental stresses when expressed in a transgenic plant. Further, it is well established in the art that mutations outside the conserved domains can also lead to protein inactivation. Mutations outside the conserved domains can result in improper protein folding resulting

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in functional inactivation and/or proteolytic degradation. The nucleic acid sequences encoding a protein which has less than 100% sequence identity to SEQ ID NO: 9 would encompass sequences that do not have activity to increase sensitivity of a plant to environmental stresses. Further, as asserted by Applicants, Guo et al. teach that there is a probability factor of 34% that a random amino acid replacement will lead to its functional inactivation. This implies that in the instant case a polypeptide even with 95% sequence identity to SEQ ID NO: 9, a probability factor of 170% (34×5) would encompass more than single amino acid changes of the encoded polypeptide SEQ ID NO: 9. Likewise, a polypeptide with 70% sequence identity to SEQ ID NO: 9, a probability factor of 1020% (34×30) would encompass more than single amino acid change of the encoded polypeptide SEQ ID NO: 9. These protein inactivation probability factors at 70% or 90% sequence identity to SEQ ID NO: 9 are significantly higher than the 76% probability factor that instant protein will retain functional activation as a result of single amino acid replacement. Examiner maintains that undue experimentation would have been required at the time claimed invention was made to use a nucleic acid sequence encoding a polypeptide which has less than 100% sequence identity to SEQ ID NO: 9 in a method of producing a stress resistant transgenic plant.

Claim 7 encompasses any nucleic acid comprising any nucleotide sequence that can hybridize to SEQ ID NO: 20 because the high stringency conditions, defined in last paragraph bridging pages 10 and 11 of specification, would encompass the hybridization of a nucleic acid sequences unrelated to SEQ ID NO: 20, which may not have the activity of increasing the sensitivity of a plant to an environmental factor.

Undue experimentation is required by skilled artisan to determine how to use said unrelated nucleic acid sequences that hybridize to SEQ ID NO: 9 in a method of increasing sensitivity of a plant to an environmental factor.

Accordingly, the rejection is maintained.

5. Claims 6-14 remain and claim 15 and newly added claims 26-33 are rejected under 35 U.S.C. 112, first paragraph rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record stated in Office action mailed February 13, 2006. Applicants traverse the rejection in the paper filed May 18, 2006.

In the paper filed May 18, 2006, Applicants argue that one would not expect substantial variation among species encompassed by claim 7, as highly stringent hybridization conditions recited yield structurally similar DNA sequences. Thus, as is the case in Example 9 of the written description guidelines, since the genus is narrow, one species (i.e., SEQ ID NO: 20) is sufficient to demonstrate possession (response, page 15, paragraph immediately preceding last paragraph). Further, Applicants argue that claim 6 is highly analogous to the claim in Example 14, which discloses a single sequence that falls within the genus covered by the claim. One skilled in the art would not expect substantial variation among species covered by claim 6 (response, page 16, lines 4-7, 2nd paragraph).

Applicant's arguments filed May 18, 2006 were fully considered but were not persuasive. Example 9 of the U.S. Patent and Trademark Office of the written description guidelines clearly discloses that hybridizing nucleic acids at highly stringent conditions were expressed and several were shown to encode proteins that bind to a dopamine receptor and stimulate adenylate cyclase activity. Thus, Example 9 clearly describes structure of genus and further correlating a significant proportion of genus to the function of stimulating adenylate cyclase activity. In the instant case, highly stringent conditions encompass conditions, for example, washing temperature (last paragraph bridging pages 10 and 11 of specification) that would allow hybridization of nucleic acid sequences (structures of the genus) that would be unrelated in function to SEQ ID NO: 20. Additionally, specification does not correlate a significant number of said structures to the function of increasing the sensitivity of a plant to an environmental factor.

Examiner disagrees that claim 6 is highly analogous to the claim in Example 14 of USPTO guidelines of written description. The claim of Example 14 of guidelines recites 95% sequence identity to SEQ ID NO: 3 which encompasses a significantly small genus of sequences, as compared to instant claim 6 which recites 70% sequence identity to instant SEQ ID NO: 9 and would encompass a significantly large genus of sequences. Furthermore, in the instant case specification fails to correlate a large number of structures of the broadly claimed genus to the function of increasing the sensitivity of a plant to an environmental factor. Applicants have failed to demonstrate that their broadly claimed genus is reduced to practice.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing.

Accordingly, rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 6-9 and newly added claims 30-33 are rejected under 35 U.S.C. 102 (b) as being anticipated by Lin et al. (NCBI, GenBank, Sequence Accession No: AC011623, Pages 1-37, Published January 2001).

The claims are drawn to an isolated nucleic acid that encodes a polypeptide as defined in SEQ ID NO: 20, or an isolated nucleic acid that under a high stringency condition hybridizes to a probe containing a sequence as defined in SEQ ID NO: 20 or a complement thereof, or a vector comprising said nucleotide sequence.

Lin et al. teach isolation and sequencing of a DNA which comprises the nucleotide sequence (positions 54079-55912) of a BAC clone having 100% sequence identity with SEQ ID NO: 20 of instant application. The nucleotide sequence from positions 54079-55912 of reference encompass instant SEQ ID NO: 20, encoding instant SEQ ID NO: 9, which is also a part of an expression vector BAC clone. Page 9 of reference teaches the coding region of the genomic clone comprising cDNA that is

100% identical to SEQ ID NO: 20 and encoding a protein having 100% sequence identity with SEQ ID NO: 9. Also see pages 28-29 of reference. BAC clone taught in the reference is an expression vector. The property of hybridization of a probe containing SEQ ID NO: 20 sequence or a complement thereof to an isolated nucleic acid is inherent to the sequence taught in the reference.

In the paper filed May 18, 2006, Applicants argue that SEQ ID NO: 20 refers to the cDNA sequence of the AtTLP9 gene. This cDNA was isolated and deposited by Applicants in the GenBank, and assigned Accession No. AF487270. The cDNA must have been isolated no later than Feb. 25, 2002. Accordingly, AC011623 does not qualify as prior art (response, page 17, lines 23 through the end of 1st paragraph on page 17).

Applicant's arguments filed May 18, 2006 were fully considered but were not persuasive. Lin et al. teachings of the instant rejection were first published in January 2001. The reference applied in Office action mailed February 13, 2006 was published October 2002. Thus the instant Lin et al. teachings qualify as 102(b) type of prior art.

Accordingly, claims 6-9 remain and newly added claims 30-33 are anticipated by the reference.

Claim Rejections - 35 USC § 103

7. Claims 6-15 and newly added claims 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (NCBI, GenBank, Sequence Accession No: AC011623, Pages 1-37, Published January 2001) and in view of Maniatis et al. (Cold Spring Harbor Laboratory, Chapter 12, Pages 404-421, New York, 1982).

The claims are broadly drawn to an isolated nucleic acid that encodes a polypeptide as defined in SEQ ID NO: 9, or an isolated nucleic acid that under a high stringency condition hybridizes to a probe containing a sequence as defined in SEQ ID NO: 20 or a complement thereof, or a vector comprising said nucleotide sequence, wherein a host cell comprises said vector, or a method of producing a polypeptide by expressing said polypeptide in a host cell comprising said vector.

Lin et al. teachings are discussed as supra.

Lin et al. do not teach a method of producing a polypeptide in a host cell.

Maniatis et al. teach a method of expressing and isolating a protein from a bacterial host cell comprising an expression vector comprising a nucleic acid sequence of interest. See the entire article.

It would have been obvious to one of ordinary skill in the art to use the method of Maniatis et al. in expressing the polypeptide taught by Lin et al. in *E. coli*, and isolating it. One of ordinary skill in the art would have been motivated to do so for the purpose of protein characterization.

In the paper filed May 18, 2006, Applicants argue that AC011623 does not qualify as prior art.

Applicant's arguments filed May 18, 2006 were fully considered but were not persuasive. Examiner maintains that AC011623 does qualify as 102(b) type of prior art as discussed above (see 35 U.S.C. 102(b) rejection).

Accordingly, claims 6-9 remain and newly added claims 30-33 as a whole are prima facie obvious over the combined teachings of the prior art.

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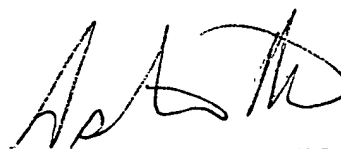
Conclusions

8. Claims 6-15 and newly added claims 26-33 are rejected. Claims 22-25 are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-5444. The examiner can normally be reached on 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**ASHWIN D. MEHTA, PH.D.
PRIMARY EXAMINER**